19) **FEDERAL REPUBLIC OF GERMANY**
/LOGO/
GERMAN PATENT OFFICE

12) **First Publication**

10) **DE 197 52 578 A1**

51) Int. Cl[6]:
F 24 C 7/10
A 61 J 1/10

21) File reference: 197 52 578.4
22) Application date: 11/27/1997
43) First publication date: 06/02/1999

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The following information has been taken from the documentation submitted by the applicant.

54) Portable heat box for the adjustment of temperatures of fluids

57) The invention relates to a portable heat box for adjusting the temperatures of fluids that are packed in bags, in particular for adjusting the temperatures of fluids intended for interperitoneal dialysis as well as of other fluids that are to be administered to the human body.
In a heat box that is known in the art the heating capacity is controlled in accordance with a time program, and the temperature is recorded using a sensor that is integrated in the heating element. By measuring the temperature on the bag and controlling the heating capacity the temperature adjustment is accelerated and safety improved.

Description

The invention relates to a portable heat box for adjusting the temperature of fluids that are packed in bags; in particular, it relates to fluids that are used for interperitoneal dialysis and for other fluids that are to be administered to the human body.

Before fluids of this kind can be brought into the human body they must be adjusted as much as possible to the body's temperature in order to prevent disturbances of the temperature control system of the human body. Especially with interperitoneal dialysis, up to 2 l of fresh dialysis solution are imported into the abdominal region of the patient. If the temperature of this fluid is not sufficiently adjusted, shock conditions may result which may, in the worst case scenarios, lead to the death of the patient.

Normally, the fresh dialysis fluid is packed in bags, for the most part these are plastic bags, that are equipped with a means for a hook-up to a permanent catheter. The exchange of the dialysis fluid occurs ordinarily up to four times per day at intervals of fours hours each. If the patient is not bound to his or her bed for other reasons, he or she would prefer not to be tied to a stationary device. Instead the patient would rather prefer to be able to conduct the fluid exchange at any location he or she might be at a given time. Consequently, there is a need for a device that will allow the patient to bring along a sufficient supply of bags, filled with fresh and temperature-adjusted fluid, for the fluid exchange.

A device of this type that is known in the art (WO-A-84/04042) consists of a carrying case, lined with a heat insulating material, that stores a bag filled with dialysis fluid. This portable case further contains an electrically heated heating element that uses a source of electric power as well as a temperature probe. With the temperature probe it is possible to control the heating capacity to the extent that a predetermined value is maintained. To heat the fluid that is usually too cold initially a program provider with a pre-selected time program can be employed to control the heating capacity. The heating energy can be supplied from the public power supply using an integrated power pack or the 12V mains of an automotive vehicle.

This device can be used to adjust the temperature of bags that had a certain temperature before they were deposited inside the device, for example room temperature. Nevertheless, it takes a fairly long time until the fluid reaches the target temperature. As a result, consequently, it may happen that no temperature-adjusted bag is available when needed. For example, the patient may forget to deposit a new bag on time, or the temperature-adjusted bag proves unfit for use, and the temperature of a new bag still needs to be adjusted. This applies in particular if the new bag was not stored at room temperature, but at a colder temperature.

To overcome these difficulties the device known in the art provides a switch that allows a manual override of the pre-selected time program. However, this may lead to the heating element being heated to an extent it damages the fluid, while the patient runs the risk of suffering burn injuries from touching the heating element.

It is therefore the subject-matter of the current invention to develop the device further, in particular in such a manner that the fluid-filled bags are heated within a short period of time from different starting temperatures to the target temperature while simultaneously avoiding the risk of overheating the fluid or exposing the patient to a risk of suffering burn injuries.

The objective is achieved with a device as claimed in the main claim.

The temperature probe touches the fluid-filled bag on the side that is opposite to the hot plate; thus, the probe measures the temperature of the fluid itself. This allows controlling the heating capacity based on the difference that exists in relation to the target temperature, making it possible to achieve a quick temperature adjustment even with very different starting temperatures.

Preferably, the inside surfaces of the top part and the bottom part of the portable case are lined with a heat insulating material. This reduces heat losses and unnecessary strain on the source of electric power, which is particularly advantageous if the power is supplied by an automotive battery. The [hot] plate that is arranged parallel to the largest cuboid surface of the device divides the interior space into two equal parts. The upper part is used for receiving the fluid-filled bag. It is open to the top and can be closed using the top part of the carrying case. The bottom part remains closed during use and is able to receive the heating element and additional components of the device.

A heating element is preferably envisioned for heating the plate, in particular a heating element that is attached to that side of the plate which is pointed away from the fluid-filled bag, or it is inserted into the plate.

Preferably, the hot plate is a metal plate, for example manufactured from aluminum. This supports the rapid and even heat transfer from the heating element to the fluid-filled bag. To protect against corrosion and for the purpose electric insulation the hot plate can be lacquered or coated.

The temperature probe can be realized as a switch that is capable of switching the heating power directly or via a relay, if need be, in several increments. Preferably, the probe acts upon a control that can be realized as an electric circuit or a microprocessor. This control [unit] controls the heating capacity based on the temperature that is measured by the temperature probe and the target temperature. This control can have any of the common features known in automatic control [technology].

In a further preferred embodied example of the invention the heating element consists of at least two electric circuits that can be switched or controlled independently of each other. This allows an incremental reduction of the heating capacity upon approaching the target temperature and promotes a faster temperature adjustment.

Due to the fact that the heating capacity is always limited based on the difference of the bag temperature in relation to the target value, the hot plate cannot be overheated after the temperature adjustment is complete, and any risk to the patient when removing the temperature-adjusted bag is precluded. To prevent the hot plate from overheating during the temperature adjustment process, preferably, a sensor is envisioned for measuring the surface temperature of the hot plate, which can also have an effect on the control, thereby limiting the heating capacity.

To further improve the safety of the device temperature limit switches are preferably envisioned in the hot plate and/or in the temperature probe that interrupt the electric heating circuits if a selected maximum temperature is exceeded. Also preferred is a switch that is activated by the deposited bag and that closes the heating circuit. This prevents heating current to flow if the device is empty, which, if not avoided, may result in undesired energy consumption and possibly overheating.

Particularly preferred is an embodiment of the device according to the invention which provides for dimensions of

the interior of the carrying case and the plate that allow several bags to be placed next to each other and have their temperatures be adjusted while positioned adjacent to each other. This way, in the morning, the patient has the chance to place the daily requirement of, for example, three bags into the device, thus having a properly temperature-adjusted bag at his or her disposal at any required time during the day. In addition, a replacement bag that is fully temperature-adjusted is thus provided as well if the bag that was intended for use should prove unfit for use e.g. because of a leak or contamination. Furthermore, such a device is also suitable for use in ambulances or by nursing services when several patients need to be cared for almost simultaneously.

Preferably envisioned in this embodied example is one switch, one temperature probe and/or one temperature limit switch for each bag.

To avoid any risk to the patient due to electric shock the heating element is preferably operated with protective extra low voltage, such as for example 12V. This voltage can be generated from e.g. a supply mains or a power pack with a transformer of the necessary safety level. Like the control unit referred to previously, this power pack can also be placed in the enclosed area underneath the hot plate. Envisioned as well are suitable means for a connection to the public power supply, such as a cable with a plug that is guided through the wall of the case. In the alternative or in addition, it is also possible to provide means for a connection to a 12V automotive power supply, such as a port in the outside wall of the carrying case or a connector cable. In case of a connection to line voltage, if necessary, a switch or a relay to separate the 12V hook-up is envisioned. It is possible to provide display instruments to indicate the operational status on the outside of the portable case. These can be, for example, incandescent bulbs, light-emitting diodes or LCDs. They are able to indicate, for example, the connection and type of the electric power supply, the absence of sufficient voltage, the flow of heating current, reaching or exceeding of the target temperature and, if necessary, any operational interruptions.

To avoid the total discharge of an automotive battery, if one is used, due to its being used in an unsupervised manner, it is also possible to envision a switch that will interrupt the connection if the voltage is insufficient.

The apparatus according to the invention can also be used for adjusting the temperature of infusion fluids, which must be brought to the temperature of the human body before they can be administered.

Furthermore, corresponding adaptations of the control elements will also render the apparatus suitable for adjusting the temperatures of other fluids, such as beverages, in particular beverages for small children.

Utilizing the subsequent embodiment the apparatus according to the invention will be illustrated in more detail. Shown are in

figure 1 a cross section of the apparatus according to the invention with the device in the folded open position,

figure 2 a longitudinal section of the bottom part and a bottom view of the top part of the apparatus according to the invention as it is folded upwards.

The embodiment of the heat box consists of a bottom part 2 and a top part 1, which are connected with each other by a hinge 3. The top part 1 can be folded down onto the bottom part 2 and fastened in place using a lock, which is not shown here, thus resulting in a portable case that can be carried using the grab handle 18. The inside walls of the top and bottom parts are lined with a heat insulating material 6. Parallel to the largest surface of the case an aluminum

plate 4 is installed that divides the inside area into two parts. On the bottom part, i.e. the side of the plate 4 that is pointed toward the closed-off part of the inside area, a heating element 5 is inserted, consisting of two heat-conducting loops that operate independently of each other. A power pack 14 and an electronic controller 15 are housed in the closed part of the inside area. A sensor 8 for the temperature measurement and a temperature limit switch 10 are located on the bottom side of the plate 4. This temperature limit switch interrupts the electric heating circuit if the temperature of the plate exceeds the pre-selected value. When this happens it can only be reactivated manually. One to three bags 11 filled with dialysis fluid can be placed onto the top side of the plate 4. A temperature probe 7 is attached to a plastic plate 12 covering the inside of the top part 1 and is snugly placed, exerting a small amount of pressure, against the bag 11 when the top part is closed. A micro-switch 13 is installed in such a way that it is activated when pressing against the bag 11. Aside from the temperature probe 7 a temperature limit switch 9 is fastened to the plastic plate 12. For a supply of electric current the power pack 14 is attached to a connector cable 16 that runs though the wall of the carrying case. In the alternative, the control 15 can be connected to 12V DC via the port 17.

As long as the carrying case is open the switch 13 interrupts the electric heating circuit. When the portable case is closed and the bag 11 deposited inside the switch 13 is closed. Now the control 15 is able to regulate the heating current in the heating element 5 according to the temperature of the bag 11 that was measured by the temperature probe 7. The two heat conducting loops of the heating element 5 are dimensioned, respectively, to deliver a capacity of 100W at 12V. If the bag temperature is far below the target temperature of 37°C, both heat conducting loops are supplied with current causing the temperature of the plate 4 to increase, possibly to up to 55°C. Once this temperature is reached, the sensor 8, which is fashioned as a bimetal switch, temporarily turns off the heating current. If the temperature of the plate continues to rise despite this, the temperature limit switch 10 is activated and permanently interrupts the electric heating circuit. It can only be reactivated manually. Simultaneously, the red light-emitting diode that is visible on the outside of the carrying case informs the user that a malfunction has occurred. As soon as the bag temperature, measured by the temperature probe 7, approaches the target value the controller 15, which is connected with the probe 7, reduces the heating capacity. Consequently, current only flows through one heat conductor loop. For additional safety another temperature limit switch 9 is installed next to the temperature probe that will permanently interrupt the electrical heat circuit if the bag temperature exceeds a value of 40°C. Another light-emitting diode, installed on the outside of the carrying case, will inform the user that the temperature was exceeded.

Additional light-emitting diodes inform the user that the bag temperature is in the target range, which means the bags are ready for use, or that the device is hooked up to sufficient voltage, or that the available voltage is too low.

To operate the embodied example of the apparatus with two or three bags additional micro-switches 13a, 13b and temperature probes 7a, 7b as well as temperature limit switches 9a, 9a are envisioned. Each switch 13, 13a, 13b can activate the electric heat circuit. Surprisingly, it was found that even if the bags had different starting temperatures, after the heating current was switched off by one of the temperature probes 7, 7a, 7b or

temperature limit switches 9, 9a, 9b, all bags were in the range of the target temperature. Evidently, the heat transfer between the bags touching each other and via the aluminum plate 4 is sufficient for the temperature adjustment.

Experiments with the apparatus described above showed that the temperature of three ordinary bags, each containing 2 l of dialysis fluid, could be adjusted in less than 45 minutes from room temperature to the target temperature. Assuming the bags were stored at colder temperatures, the time to adjust their temperatures would not be much longer because the full heat capacity would be activated initially.

List of Reference Symbols

1 Top part
2 Bottom part
3 Hinge connection
4 Hot plate
5 Heating element
6 Heat insulating material
7 Temperature probe
8 Sensor for temperature measurements
9 Limit switch on temperature probe
10 Limit switch on the plate
11 Bag filled with fluid
12, 12a Plastic strap
13 Micro-switch
14 Power pack
15 Controller
16 Mains connector
17 Port for 12V connection
18 Grab handle

Patent Claims

1. Portable heat box for adjusting the temperature of fluids packed into bags, in particular of fluids intended for intraperitoneal dialysis, consisting of a cuboid-shaped carrying case that is comprised of a top part (1) and of a bottom part (2), of at least one hot plate (4), arranged in the bottom part (2) of the carrying case and parallel to the largest cuboid surface of the portable case, and a least one temperature probe (7), arranged in the top part (1) in such a manner that, if the carrying case is closed, it touches a fluid-filled bag (11) which is positioned on the hot plate (4), in particular on the side of the bag that is opposite to the side that points towards the [hot] plate.
2. Heat box as claimed in claim 1 wherein the inside surfaces of the top part and the bottom part are lined with a heat insulating material (6).
3. Heat box as claimed in one of the previous claims wherein the plate (4) can be heated using a heating element that is attached to or integrated in the bottom side of the plate.
4. Heat box as claimed in one of the previous claims wherein the hot plate (4) is a metal plate.
5. Heat box as claimed in one of the previous claims wherein the box contains a controller (15) that is connected with the electric heating current and the temperature probe (7) and controls the heating capacity in based on the temperature that is measured by the temperature probe (7) and the target temperature.
6. Heat box as claimed in one of the previous claims wherein the heating element (5) is comprised of at least two separate electric heating circuits that can be switched and/or controlled independently of each other.
7. Heat box as claimed in one of the previous claims wherein the box contains a sensor (8) for measuring the surface temperature of the plate (4).
8. Heat box as claimed in one of the previous claims wherein the box

contains a switch (13) that is activated by the inserted bag.

9. Heat box as claimed in one of the previous claims wherein the plate (4) and/or the temperature probe (7) contain(s) (a) temperature limit switch(es) (9, 10) that interrupt the heating circuits if a selected maximum temperature is exceeded.
10. Heat box as claimed in one of the previous claims wherein the inside area of the carrying case and of the plate (4) are dimensioned in such a way as to allow the placement of several bags (11), one adjacent to the other.
11. Heat box as claimed in claim 10 wherein each bag that is to be inserted has allocated, respectively, one switch (13, 13a, 13b) and one temperature probe (7, 7a, 7b) and/or temperature limit switch (9, 9a, 9b).
12. Heat box as claimed in one of the previous claims wherein the heating element (5) is operated with protective extra low voltage.
13. Heat box as claimed in one of the previous claims wherein the box contains means (16) for connecting the box with public current and a power pack (14) in order to transform the line voltage into protective extra low voltage.
14. Heat box as claimed in one of the previous claims wherein the box contains the means (17) for a connection to a 12V automotive current line.

In connection with the above 2 page(s) of drawings

Drawings Page 1/2

Number:	**DE 197 52 578 A**
Int. Cl. 6:	**F24 C 7/10**
Date of first publication:	June 2, 1999

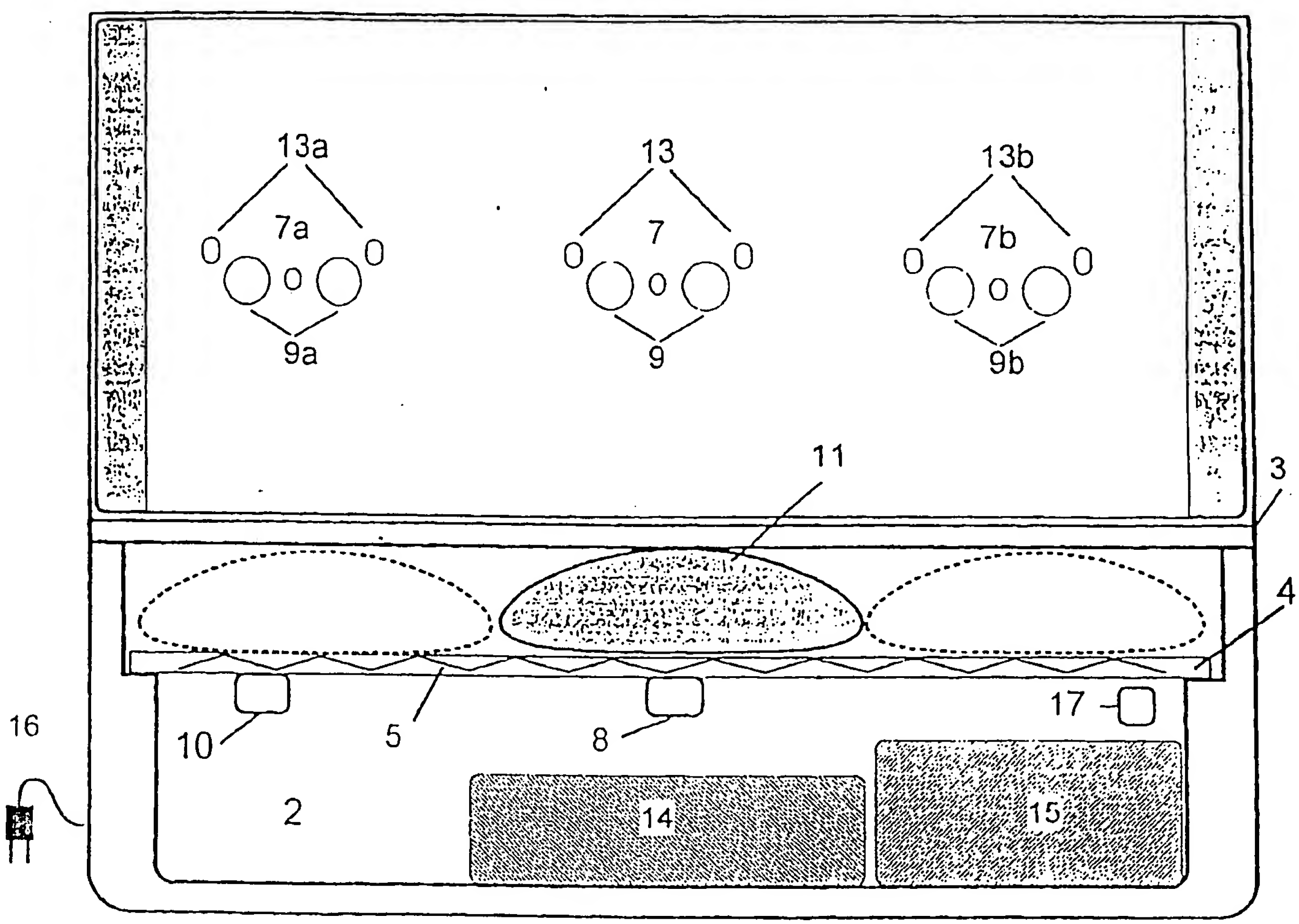

Fig. 2

Drawings Page 2/2

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Date of first publication: June 2, 1999

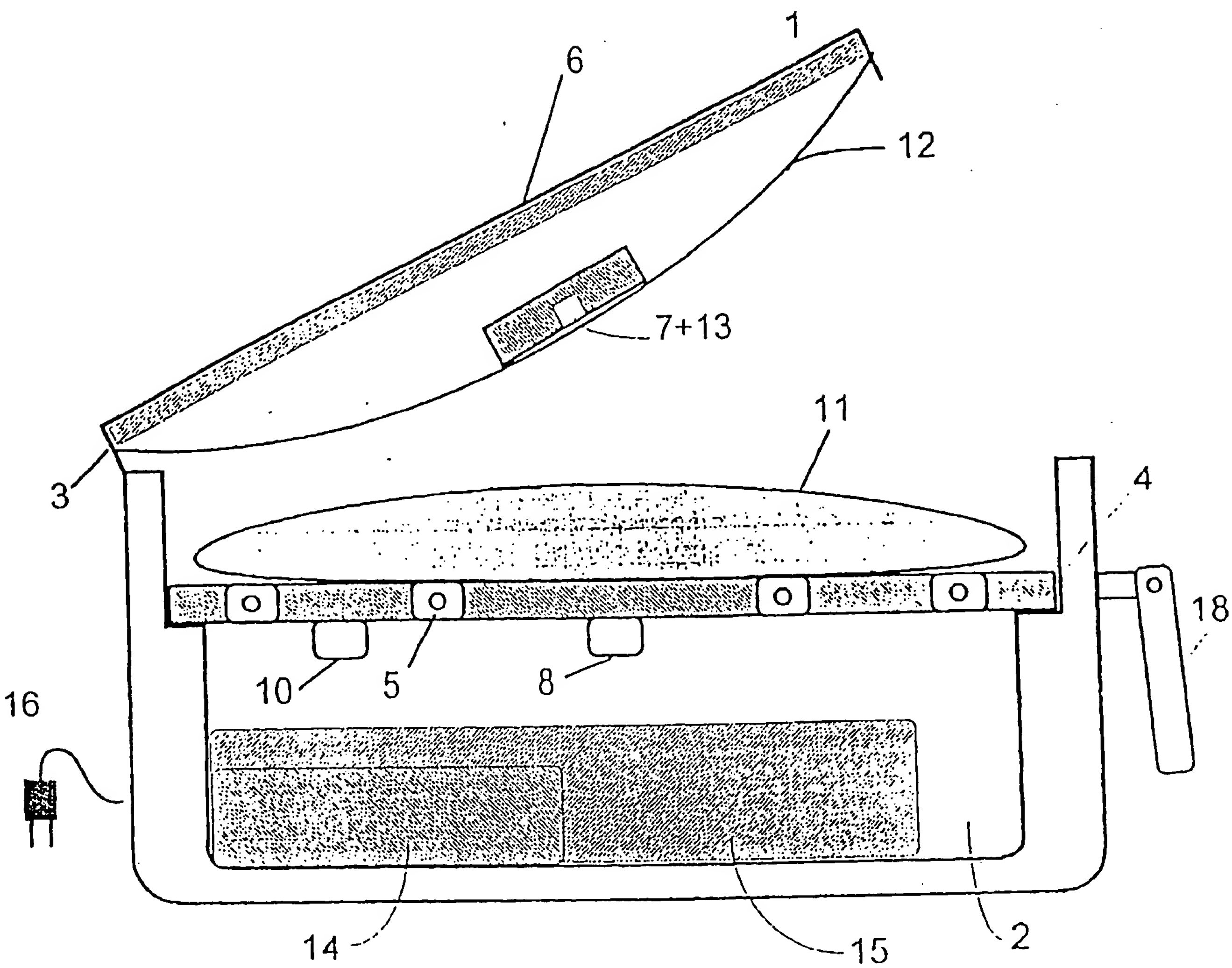

Fig. 1